



Department of Health and Human Services

Public Health Service

Food and Drug Administration
Rockville, MD 20857

MAY 14 2010

Re: Entereg
Docket Nos. FDA-2009-E-0073
FDA-2009-E-0015

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the patent term extension applications for U.S. Patent Nos. 5,250,542 and 5,434,171 filed by Eli Lilly and Company under 35 U.S.C. § 156. The patents claim Entereg (alvimopan), new drug application (NDA) 21-775.

In the October 9, 2009, issue of the Federal Register (74 Fed. Reg. 52241), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before April 7, 2010, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad
Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Donald J. Bird
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